



PCT/GB 2004 / 0 0 0 1 2 9



INVESTOR IN PEOPLE

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH
RULE 17.1(a) OR (b)

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

REC'D 24 FEB 2004

WIPO PCT

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

Dated 17 February 2004

BEST AVAILABLE COPY



The
Patent
Office

15JAN03 1776914-3 002096
P01/7700 0.00-0300786.1

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP9 1RH

1. Your reference	42261		
2. Patent application number (The Patent Office will fill in this part)	0300786.1		14 JAN 2003
3. Full name, address and postcode of the or of each applicant (underline all surnames)	Stephen George Edward BARKER, 16 Wilks Gardens, Shirley, Surrey, CR0 8UJ.		
Patents ADP number (if you know it)			
If the applicant is a corporate body, give the country/state of its incorporation	7220932004		
4. Title of the invention	Laparoscopic Port Hernia Device.		
5. Name of your agent (if you have one)	J.B. King, KINGS PATENT AGENCY LIMITED		
"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)	73 Farringdon Road, London, EC1M 3JQ, United Kingdom		
Patents ADP number (if you know it)	1008001		
6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number	Country	Priority application number (if you know it)	Date of filing (day / month / year)
7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application	Date of filing (day / month / year)	
8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if: a) any applicant named in part 3 is not an inventor, or b) there is an inventor who is not named as an applicant, or c) any named applicant is a corporate body. See note (d))	No		

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description 7

Claim(s) -

Abstract -

Drawing(s) 2 + 2 *KE*

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for preliminary examination and search (*Patents Form 9/77*)

Request for substantive examination (*Patents Form 10/77*)

Any other documents
(please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

J.P. King
J.P. King (Agent)

Date 14/01/03

12. Name and daytime telephone number of person to contact in the United Kingdom

Voice: 020 7248 6161

Fax: 020 7831 0926

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.*
- Write your answers in capital letters using black ink or you may type them.*
- If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.*
- If you have answered "Yes" Patents Form 7/77 will need to be filed.*
- Once you have filled in the form you must remember to sign and date it.*
- For details of the fee and ways to pay please contact the Patent Office.*

Title:**Laparoscopic Port Hernia Device.**

This invention relates to a laparoscopic surgical mesh and an applicator primarily intended for internal closure of an incision for to prevent formation of a port-site hernia following a surgical procedure, or operation. Secondly, prevention of formation of internal organ adhesion at the operation site may be helped.

Laparoscopic surgery is used increasingly and requires the provision of one or more tunnels through all layers of the body wall, forming ports through which a surgical procedure is effected remotely using various instruments, a telescope or camera and a light source. For a laparoscopic cholecystectomy, for example, three such ports are used typically, with 0.5 to 1 cm incisions down through the layers of abdominal wall, with one port very often through the umbilicus. Typically each port is closed, following the procedure, with outer skin stitches only, thus leaving the deeper layers to heal themselves. This small incision has the potential, later, to become an incisional or port hernia. Internally, the unrepaired port opening can allow, potentially, a bowel portion to herniate through or may offer an adhesion point for bowel, with the potential then for bowel obstruction.

It is a primary objective of this invention to provide a surgical mesh and applicator for use in the closure of port incisions, such as those following laparoscopic procedures and which is simple to use through the same laparoscopic port lumen and which has a minimum of components.

Another object is to provide a collapsed mesh structure which may be

readily passed down the port and then opened out internally across the opening.

According to one aspect of this invention there is provided an applicator assembly for use in applying a sheet of surgical material through an opening to
5 bridge the remote internal termination of the opening, the assembly comprising;

- a) a deployment sleeve;
- b) a plunger for location within the sleeve, to extend from the proximal to the distal end thereof;
- c) a sheet of surgical material which can be folded, or collapsed, for
10 location at and within the distal end of the deployment sleeve;
- d) an actuating means operative to unfold or erect the sheet following
expulsion from the distal end of the deployment sleeve through
longitudinal movement of the plunger and, optionally,
- e) a further means such as a suture, operative to apply a pull force to
15 the sheet following deployment.

In this arrangement, and according to the invention, the sheet material is encased and protected within the deployment sleeve during the manipulation procedure to position the sleeve at the termination of the opening after which the sheet is expelled by the plunger to be erected to close behind and over the
20 internal area of the opening.

The sheet of surgical material will generally be of a known surgically compatible mesh such as polypropylene most likely including a PTFE or similar non-stick material on one surface, that is the innermost facing surface, adjacent

the applicator. The material is normally a flat flexible sheet, for example circular, and may include radial ribs forming more rigid but resilient arms through which, when the sheet is forced to a collapsed or folded configuration, the sheet is caused to open out to restore the flat form. This action may be likened to the opening of an umbrella and a feature is that the opening can be effected through the properties of the sheet itself not requiring additional mechanical components. As an alternative, or in addition, opening is effected through a suture which pulls the sheet upward towards the applicator.

In an embodiment, the ribs have preformed fold creases to facilitate collapse to a predetermined configuration. Alternatively, the ribs may have a "memory" acting to restore the sheet to a flat form. Following deployment of the sheet the opening thereof may be effected or assisted by a separate actuating means which may comprise a suture needle, with or without an attached suture, extending through the plunger from the proximal to the distal end of the sleeve and connecting with the sheet. The suture is arranged so that a pulling force applied thereto opens the sheet. The suture may then be removed, or severed, or broken. In this embodiment, the suture may be used for applying traction to position the sheet and to close the wound using the attached needle.

According to another aspect of this invention, there is provided a sheet of surgical material including ribs or radially extending formations which may be resiliently flexed and which, on restoration, extend the sheet from a folded, pleated or crumpled form to a flat and self-supporting form.

According to yet another aspect of this invention there is provided a sheet of surgical material including radial ribs each rib being hinged to allow outer parts of the sheet to be folded inwards into a conical shape, the sheet

being extended to a flat form by an actuating means. The sheet in these embodiments thus opens in the manner of an umbrella.

To explain the features of this invention further reference is now made to the drawings showing an embodiment by way of an example. In the drawings:

5 Fig. 1 shows a surgical mesh and an applicator in accordance with this invention in partial sectional view and in a first assembly stage,

Fig. 2 shows the applicator in a loaded stage,

Fig. 3 shows the applicator during initial deployment,

10 Fig. 4 shows the applicator with the sheet partially opened,

Fig. 5 shows the applicator with the sheet fully opened,

Fig. 6 shows the sheet after withdrawal of the applicator, and

Fig. 7 shows in diagrammatic form a closure.

Referring to Fig. 1 of the drawings, an applicator assembly for use in
15 applying a sheet of surgical material through an opening to bridge the remote internal termination of the opening has a deployment sleeve 1, a plunger 2 for location within the sleeve 1 and which has a length sufficient to extend from the proximal to the distal end of the sleeve and a sheet of surgical material 3 which can be folded or collapsed to a conical form as shown for location at and within
20 the distal end of the deployment sleeve. The material can equally well be located the other way round, that is with the apex adjacent the plunger 2. An actuating means 4 comprising a suture is provided operative to unfold or erect the sheet 3 following expulsion from the distal end of the deployment sleeve 1

through longitudinal movement of the plunger 2. The sheet 3 is conveniently circular, typically, of some 3 cm or so in diameter. The inner facing surface will include a PTFE coating or layer to inhibit adhesion of tissue, notably bowel. The outward facing surface will be of uncoated polypropylene mesh or similar, to facilitate incorporation into the body wall tissues.

The sheet 3 includes radial ribs 5 connected along their length to the sheet except at an inner region 5a defined by a hinge 5b where the ribs are free and joined at the ends to a collar 5c through a further hinge connection (see Figs. 4 to 6). The hinge connection may be formed by crease lines or zones of reduced thickness or width. The ribs preferably comprise a biologically absorbable polymer material, for example Vycryl® or PDS.

The suture 4 forming the actuating means connects to the centre of the sheet and passes through the collar 5c and the plunger 2 to the proximal end.

Laparoscopic ports are generally 0.5 to 1.0 cm in nominal diameter and thus sleeve 1 is appropriately dimensioned to pass down the port device. The suture may be absorbable Vycryl® or similar and pass all the way through the plunger to a needle. At the termination of the laparoscopic procedure following withdrawal of instruments the applicator assembly will be fed through the port device. The outer sleeve may have an externally placed flange to control the length of insertion in the port and the plunger may likewise have a flange to control the position in the sleeve.

The operation is as follows:-

The sleeve 1 includes the folded or collapsed mesh 3 previously located in the distal end with suture 4 fitted, and then receives the plunger 2 (Fig. 1)

The plunger 2 is then pushed down onto the collar 5c (Fig. 2)

Deployment is effected after location through a laparoscopic port device by pushing down the plunger to expel the mesh out of the end of the sleeve 1 (Fig. 3)

5 Suture 4 is then pulled tight causing the mesh 3 to open through the unfolding of the rib parts 5 and 5a (Fig. 4) and to present a load dissipating support mesh closing the incision.

With the mesh now fully unfolded (Fig. 5) the sleeve and plunger may be withdrawn leaving the mesh 3 in position (Fig. 6).

10 Fig. 7 shows in a diagrammatic way the installed mesh wherein G represents the gut, as example, and A represents the abdominal wall.

In one arrangement the suture is connected to a straight needle, such that the needle can pass down the lumen of the plunger, allowing the placement system to be discarded. Alternatively, the outer sleeve and plunger
15 could be perforated along their entire lengths, such that both could be pulled apart, down the perforation and discarded. In either case, the placement system would be removed from the port device and the port device removed secondarily. If no needle was present then all devices could be removed simultaneously, with the thread used for traction only, being tied off in to the
20 wound by a second wound closure suture used independently. The suture could be used for directly to close the wound, if desired.

If the placement system outer sleeve had no flange then the port device could be slid off over it, prior to mesh deployment.

In a modification of this invention and for use in similar scenarios to

laparoscopic ports, e.g. at an appendicectomy, a larger sheet of mesh, with the inner aspect covered with PTFE (Teflon) could be placed to prevent post-operative adhesion of bowel. This mesh could have one, two or more sutures attached along its length. This arrangement would utilise the sheet which
5 unfolds but the use of the applicator would not be essential in this case.

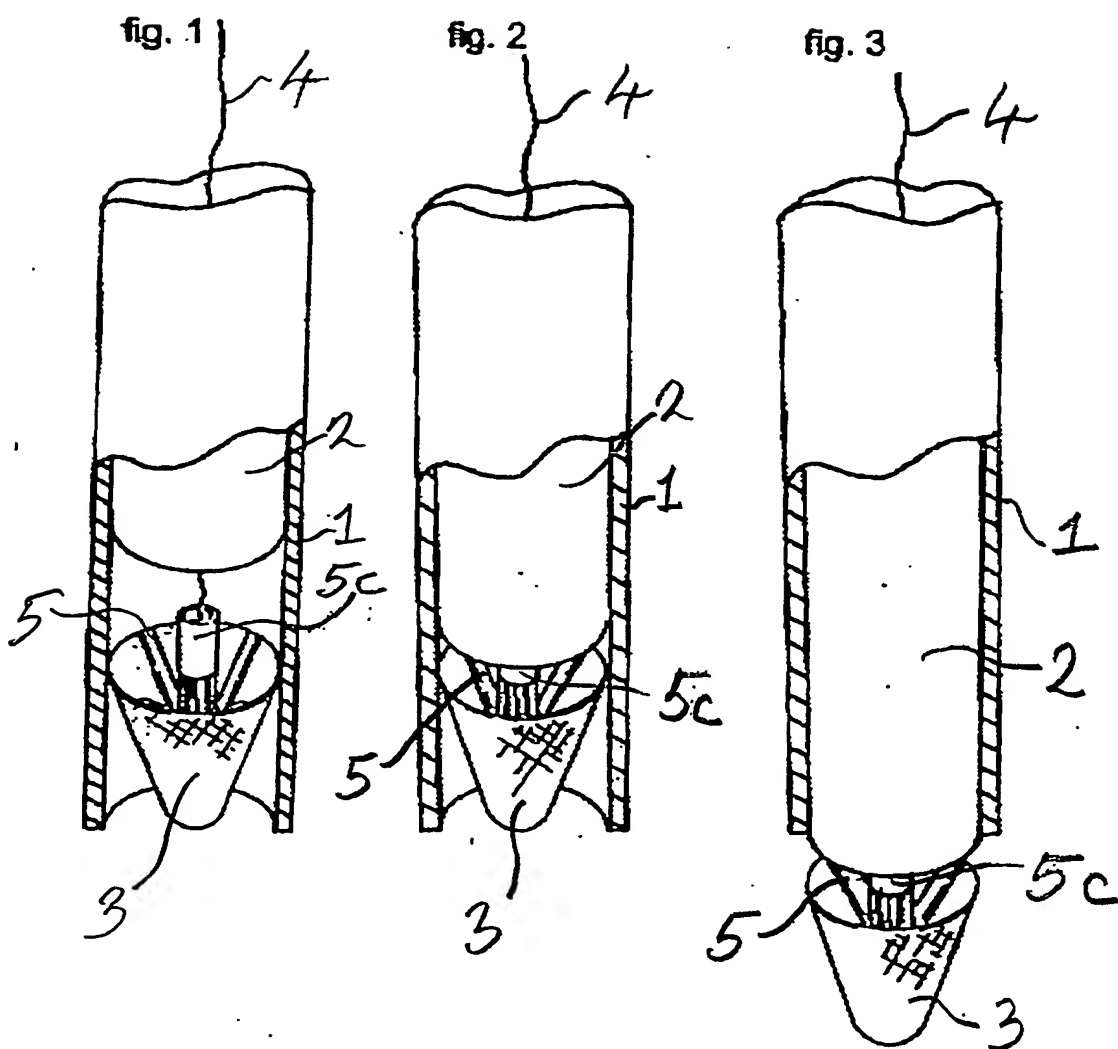
When placed at the end of (open) surgery, the mesh overall would help dissipate load at the wound site, helping prevent incisional hernia formation.

The PTFE inner aspect would help prevent bowel or organ adhesion. The polypropylene mesh outer aspect would help incorporation into the bowel wall.

10 The attached sutures could be pulled, to tension the mesh against the inside of the abdominal wall. Attached needles could then be used to closed muscle layers, etc. leaving the skin for closure only. Having different numbers of needles along a length of mesh means that the mesh could be cut to any length

required. Longer mesh would necessarily be broader also.

1/2



2/2

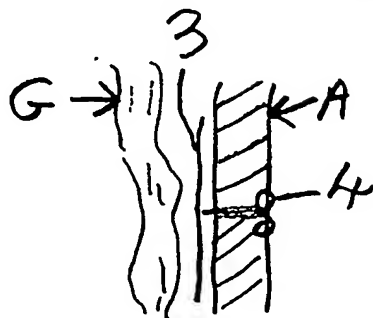
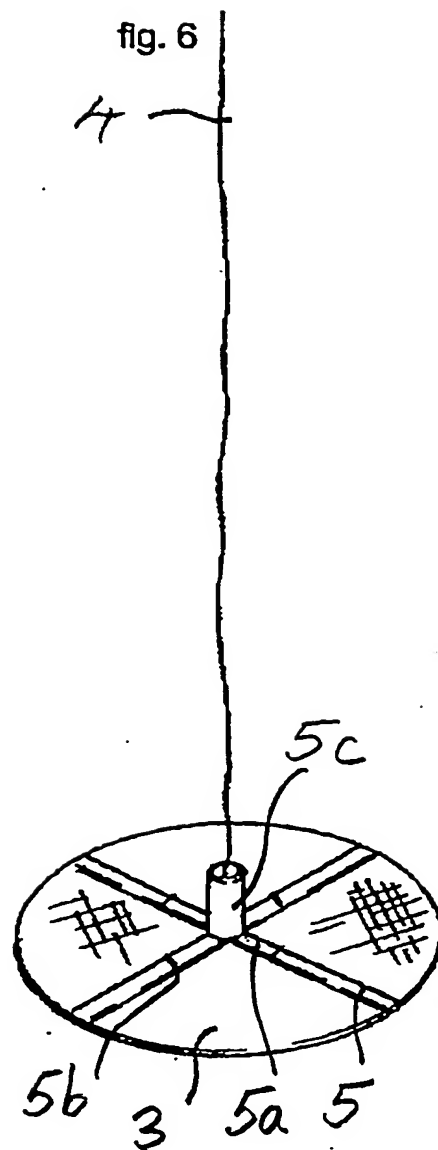
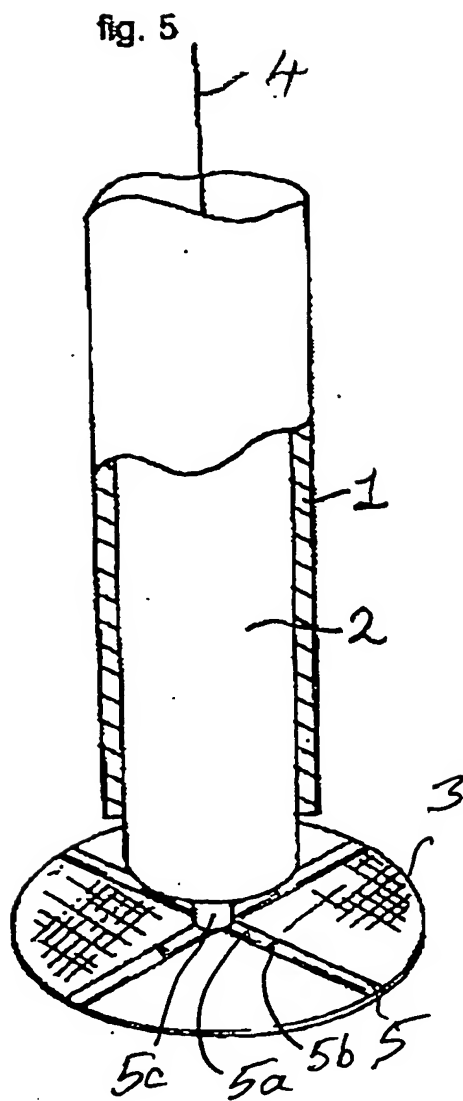
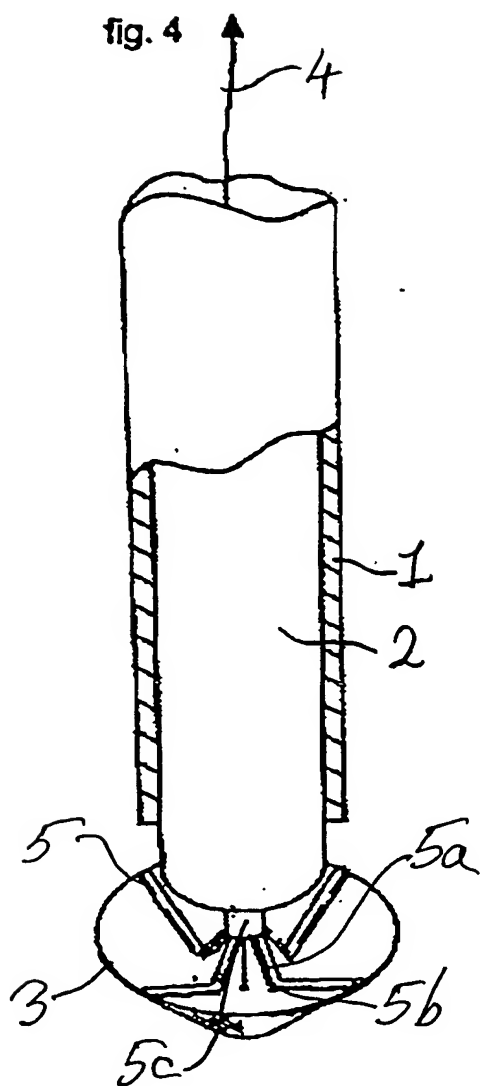


FIG. 7

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☒ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☒ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.